hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, and cosmetic exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act (the act) or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act.* Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, except that records pertaining to the export of foods and cosmetics under section 801(e)(1) of the act shall be kept for 3 years after the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications: The records must contain sufficient information to match the foreign purchaser's specifications to a particular export;

(2) Records demonstrating that the product does not conflict with the laws of the importing country: This may consist of either a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export: This may consist of copies of any labels or labeling statements, such as ''For export only,'' that are placed on the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials.

(c) *Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biological product under section 351(h) of the Public Health Service Act shall maintain, for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records demonstrating that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Records demonstrating the distribution of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product and other records demonstrating that the exported partially processed biological product is intended for further manufacture into a final dosage form outside the United

States; this may include a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biological products, and devices exported under section 802 of the act.* (1) Persons exporting a human drug, biological product, or device under section 802 of the act, other than a drug, biological product, or device for investigational use exported under section 802(c) of the act, or a drug, biological product, or device exported in anticipation of marketing authorization under section 802(d) of the act, shall provide written notification to FDA. The notification shall identify:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM–610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737;

(iii) For devices—Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

[66 FR 65447, Dec. 19, 2001]

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

Subpart A—General Provisions

Sec.

Subpart B—Human and Animal Foods

Subparts C—E [Reserved]